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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,259	04/23/2002	George R. Newkome	0152.00427	9419

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,259

Applicant(s)

NEWKOME, GEORGE R.

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RD

DETAILED ACTION

1. Claims 4 and 5 are pending and are examined.

Priority

2. Upon further consideration and consultation, the holding that it is improper for the instant application to claim to be both a national stage entry under 35 USC § 371 and a continuation-in-part, under 35 USC §§ 111 and 120, is withdrawn. The examiner sincerely regrets any inconvenience to the applicant that this has caused.

3. It is recommend that the first line of the specification state:

The present application is the National Stage, Under 35 U.S.C. 371, of PCT/US00/40431, filed July 20, 2000, which claims the benefit of United States Provisional Patent Application Serial No. 60/145,785, filed July 27, 1999, and is also a continuation-in-part of United States Patent Application of 09/646,737, filed November 22, 2000, which claims benefit of United States Provisional Patent Application No. 60/079,413, filed March 26, 1998, all of which are incorporated herein by reference.

Information Disclosure Statement

4. The information disclosure statements filed 2/7/2003, 1/13/2003 and 12/12/2002 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 for the reasons set forth in the previous Office action. The information disclosure statements have been placed in the application file, but the information referred to therein, *as pertaining to the publications named in the previous Office action*, has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all

certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609

¶ C(1).

Drawings

5. The replacement drawing of the figures, entered on 4/26/2005, is acknowledged.

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Amended claim 4 depicts the following structure:



The specification as filed does not appear to disclose said structure.

Applicant argues that the structure set forth in claim 4 is disclosed in Figure 3 of the specification. In particular, Applicant states that formula 31 sets forth the specific structure.

Applicant's arguments have been carefully considered and are not found persuasive. Formula 31 does not depict a structure having a double bond between a nitrogen atom and an oxygen atom, as is found in amended claim 4. Moreover, formula 31 does not depict a terminal nitrogen atom with five bonds, i.e., 2 bonds to hydrogen, and 3 bonds to the bracketed structure of amended claim 4. In fact, formula 31 of Figure 3 depicts an amine bonded to a carbon atom, said carbon atom also bonded to 3

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identical residues terminating in O-R. Therefore the objection to the specification is maintained.

7. There does not appear to be support for the amendments to the specification, filed 4/23/2002 at p. 5 of the instant application ("wherein X is an integer from 1 to -3-"), as stated in the previous Office action.

Applicant points to three branching structures, as depicted in compounds 29 and 33 of redrawn Figure 3, and in Figure 4, compound 36, for support to the proposed amendment to the specification. However, there does not appear to be a depiction of compounds 29 and 33 of Figure 3. Compounds 29, 33 and 36 do not depict a compound having three alkyl chain residues attached to a nitrogen atom, which is in turn attached to a carbon atom. Also, upon further inspection, compounds 29, 33 and 36 do not depict a compound having a carbon of an alkyl (bonded to two other carbon atoms) that has a double bond to an oxygen atom and a bond to NH, thereby showing 5 bonds, as depicted in the formula bound on page 5 of the instant specification.

Therefore this objection to the specification is maintained.

8. In view of the difficulties manifest in evaluating the hand drawn formulas found on pages 5 and 6 (and elsewhere in the application), the specification is object to in regards to those hand drawn formulas. Correction is required.

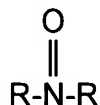
Maintained Claim Rejections - 35 USC § 112, First Paragraph

9. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection maintains the reasons of record as set forth in the previous Office action.

Response to Arguments

Applicant's arguments filed 4/26/2005 have been fully considered but they are not persuasive.

Applicant argues that the structure:



was known in the dendrimer arts, and points to publications of Sheenan et al. and Bodansky and Bodansky for support of this proposition.

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). MPEP 2145. Applicant's representative has not supplied the relied upon publications of Sheenan et al. (1955) and Bodansky and Bodansky (1984). The mere assertions of counsel that the structure

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was known in the dendrimer art, without the provision of objective, factual evidence, is not persuasive.

Furthermore, the examiner respectfully submits that the specification as filed does not provide guidance and direction for the making and using of dendrimers comprising the aforementioned structure, which depicts a nitrogen atom double bonded to an oxygen atom and where said nitrogen atom is also bonded to two carbon atoms (see also the above objection to the specification). Therefore undue experimentation would be required to make and use the claimed invention.

New Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. This rejection is necessitated by applicant's amendments to the claims, entered 4/26/2005.

Applicant has not pointed to where in the specification support may be found for the amendments to the formulae depicted in claims 4 and 5. It is unclear that the redrawn formulae find support in the previous, hand drawn, formulae of the claims, and

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which said redrawn formulae replace. The claims are given their broadest reasonable interpretation consistent with the disclosure. However the examiner finds that the previous hand drawn formulae were so unclear as to be difficult to interpret for specific support.

Maintained Claim Rejections - 35 USC § 112, Second Paragraph

11. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection maintains the reasons of record as set forth in the previous Office action.

Response to Arguments

Applicant argues that the amendments to the claims, particularly the amendments to the formulas shown in the claims, remove the rejections under 35 USC 112, second paragraph.

Applicant's arguments filed 4/26/2005 have been fully considered but they are not persuasive.

Claims 4 and 5 depict drawings of chemical structures remain difficult to interpret. For example, it is difficult to reconcile the position, number and identity of the various atoms in the depicted compounds. The claims are thereby rendered vague and indefinite.

Claim 4, depicts a drawing that shows an intersection of a straight line crossing an open bracket, "[", which renders the claim vague and indefinite, because the triple

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repeating unit is bound to the amine Nitrogen (thereby forming a nitrogen atom with 5 bonds).

Claim 5, depicts in the second drawing that shows an amended formula depicting an oxygen atom bonded to 4 carbon atoms.

Claim 5, in the third drawing, depicts an amended formula depicting the core that is yielded as showing a carbon atom with 5 bonds, i.e., one bond to a C and 4 carbon-oxygen binds attaching the residue terminating in K.

Conclusion

12. Claims 4 and 5 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

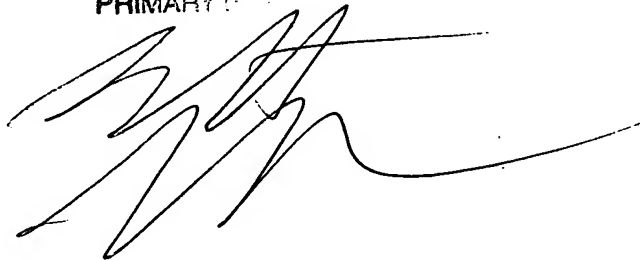
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

BENNETT C. L.
PRIMARY EXAMINER

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A handwritten signature in black ink, appearing to be 'MSH', written over the printed name of Bennett C. L.